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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,381	02/06/2002	Mark A. Goldsmith	GLAD001CON	2681

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,381

Applicant(s)

GOLDSMITH ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 28-39 and 49-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28-39, 49-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of group I claims 28-39 and 49-52 with traverse, and the request to combine claims 53 and 54 with group I, is acknowledged. Claims 38, 39, and 49-54 have been amended, and claims 40-48 have been canceled. The purposed species election in paper No. 7 is not fully responsive to the original restriction requirement. However, upon further review and consideration, previous restriction requirement has been modified as following.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:
 - I. Claims 29, 33-36, 38, and 51 are drawn to a transgenic rat, whose genome comprising a first transgene encoding a human CD4, a second transgene encoding a human chemokine receptor CCR5, and a third transgene encoding a polypeptide subunit of human elongation factor P-TEFb, which interacts with an HIV sequence. Claims are further drawn to cells isolated from the transgenic rat, and a method of making the rat. Classified in class 800, and subclass 13.
 - II. Claims 30, 33, 34, 36, 39, 51, and 54 are drawn to a transgenic rat, whose genome comprising a first transgene encoding a human CD4, a second transgene encoding a human chemokine receptor CCR5, and a third transgene encoding a polypeptide Cyclin T, which interacts with an HIV sequence. Claims

Art Unit: 1632

are further drawn to cells isolated from the transgenic rat, and a method of making the rat. Classified in class 800, subclass 13 and 21.

- III. Claims 29, 33, 38, 49, 50, 52 are drawn to a transgenic rat, whose genome comprising a first transgene encoding a human CD4, a second transgene encoding a human chemokine receptor CXCR4, and a third transgene encoding a polypeptide subunit of human elongation factor P-TEFb, which interacts with an HIV sequence. Claims are further drawn to cells isolated from the transgenic rat, and a method of making the rat. Classified in class 800, and subclass 13.
- IV. Claims 30, 33, 38, 39, 49, 50, 52 are drawn to a transgenic rat, whose genome comprising a first transgene encoding a human CD4, a second transgene encoding a human chemokine receptor CXCR4, and a third transgene encoding a polypeptide Cyclin T, which interacts with an HIV sequence. Claims are further drawn to cells isolated from the transgenic rat, and a method of making the rat. Classified in class 800, and subclass 13.
- V-XII. Groups V-XII, claims 29, 33, 38, are drawn to a transgenic rat, whose genome comprising a first transgene encoding a human CD4, a second transgene encoding one of the human chemokine receptor selected from the group consisting of CCR3, CCR2B, CXR3, CCR8, GPR15, STRL33, APJ, and LTB4, and a third transgene encoding a polypeptide subunit of human elongation factor P-TEFb, which interacts with an HIV sequence. Claims are further drawn

to cells isolated from the transgenic rat, and a method of making the rat.

Classified in class 800, and subclass 13.

XIII-XX. Groups 13-20, claims 30, 33, 39, are drawn to a transgenic rat, whose genome comprising a first transgene encoding a human CD4, a second transgene encoding a human chemokine receptor as recited in claim 33 (i.e. selecting one from the group consisting of CCR3, CCR2B, CXR3, CCR8, GPR15, STRL33, APJ, and LTB4), and a third transgene encoding a polypeptide Cyclin T, which interacts with an HIV sequence. Claims are further drawn to cells isolated from the transgenic rat, and a method of making the rat. Classified in class 800, and subclass 13

Claims 28, 31, 32, 37, and 53 link inventions I-XX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 28, 31, 32, 37, and 53. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-XX and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to different transgenic rats, i.e. rats whose genome comprises different human chemokine receptor, such as CCR5 or CXCR4; and different polypeptides that interact with HIV, such as P-TEFb and cyclin T. The rats having different combinations of the first, second, and third transgene in their genome, would have different genotype and phenotype, thus, they are patentably distinct in terms of chemical structure and biological function and require different technical consideration.

The differences of the Inventions I-XX are further underscored by their divergent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Invention groups I-XX are further drawn to distinct species of rat whose genome are homogenous for CD4, or homogenous for a chemokine receptor, or homogenous for both CD4 and a specific chemokine receptor. If one of the invention groups I-XX is elected, further election of a species drawn to a particular type of homogeneity is necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic with respect to the homogeneity.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers

Application/Control Number: 10/072,381
Art Unit: 1632

Page 8

for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li
Examiner
Art Unit 1632

QJL
September 5, 2003